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Research Article

RP-HPLC Method for Simultaneous Estimation of Tamsulosin and Finasteride in Bulk and Pharmaceutical Dosage Forms

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Abstract

A new method was established for simultaneous estimation of Tamsulosin and Finasteride by RP-HPLC method. The chromatographic conditions were successfully developed for the separation of Tamsulosin and Finasteride by using Agilent C18 column (4.6×150mm) 5µ, flow rate was 1ml/min, mobile phase ratio was (60:40 v/v) methanol: phosphate buffer, detection wavelength was 256nm. The instrument used was WATERS HPLC Auto Sampler, Separation module 2695, photo diode array detector 996, Empower-software version-2. The retention times were found to be 2.327 mins and 4.342 mins. The % purity of Tamsulosin and Finasteride was found to be 99.84% and 100.14% respectively. The system suitability parameters for Tamsulosin and Finasteride such as theoretical plates and tailing factor were found to be 2937, 1.3 and 2300 and 1.3, the resolution was found to be 4.6. The analytical method was validated according to ICH guidelines (ICH, Q2 (R1)). The linearity study of Tamsulosin and Finasteride was found in concentration range of 50µg-250µg and 10µg-50µg and correlation coefficient (r^2) was found to be 0.999 and 0.999, % recovery was found to be 100.07% and 100.06%, %RSD for repeatability was 0.3 and 0.39, % RSD for intermediate precision was 0.1 and 0.16 respectively. The precision study was precise, robust and repeatable. LOD value was 3.041 and 3.08 and LOQ value was 9.79 and 10.37 respectively. Hence the suggested RP-HPLC method can be used for routine analysis of Tamsulosin and Finasteride in API and Pharmaceutical dosage form.

Keywords: C18 column, Phosphate buffer, Tamsulosin and Finasteride, RP-HPLC

Article Info

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Contents

1. Introduction

Tamsulosin is a selective alpha-1A and alpha-1B adrenoceptor antagonist that exerts its greatest effect in the prostate and bladder, where these receptors are most common. It is indicated for the treatment of signs and symptoms of benign prostatic hypertrophy. Antagonism of these receptors leads to relaxation of smooth muscle in the prostate and detrusor muscles in the bladder, allowing for better urinary flow. Other alpha-1 adrenoceptor antagonists developed in the 1980s were less selective and more likely to act on the smooth muscle of blood vessels, resulting in hypotension. **Finasteride** is an antiandrogenic compound that is used for the treatment of symptomatic benign prostatic hyperplasia (BPH) and male pattern hair loss in adult males by inhibiting Type II 5-alpha reductase.

2. Methodology

Instrumentation

The instrument used was HPLC Alliance Waters model No. 2695 separation module. 2487UV detector, Software-EMpower. The stationary phase used was Agilent C18 column (4.6×150mm) 5µ. Semi micro balance –Model number Sartorius ME235P, Sonicator (Enertech)-SE60US, pH meter Lab India, UV/VIS spectrophotometer UV3000 Lab India Software-UVWin5.

Materials and reagents

Tamsulosin and Finasteride were gift samples provided by Dr.Reddy's Laboratories Hyderabad, Potassium dihydroge northophosphate, sodium perchlorate, Perchloric acid, Ortho phosphoric acid, Methanol, Acetontrile, Water were supplied by Merck.

Method development

Three trials were made by changing the mobile phase ratios and solvents Methanol: Phosphate buffer P^H3 (70:30) Methanol: Sodium acetate P^H 4 (60:40)Methanol: Ammonium acetate P^H3 (70:30) . Finally, the mobile phase optimized mobile phase ratio was (60:40 v/v) methanol: Phosphate buffer pH 3.0.

Chromatographic conditions

The chromatographic conditions were successfully developed for the separation of Tamsulosin and Finasteride by using AgilentC18 column (4.6×150mm) 5µ, flow rate was 1ml/min, mobile phase ratio was (60:40 v/v) methanol: Phosphate buffer pH 3.0, detection wavelength was 256 nm.

3. Results and Discussion

Table 1 Linearity results for Tamsulosin

S.No	Linearity Level	Concentration	Area
1	I	50 ppm	892464
2	II	100 ppm	1904884
3	III	150 ppm	2906620
4	IV	200 ppm	3800672
5	V	250 ppm	4738193
Correlation Coefficient			0.99932

Table 2 Linearity results for Finasteride

S.No	Linearity Level	Concentration	Area
1	I	10 ppm	907953
2	II	20 ppm	1730043
3	III	30 ppm	2553693
4	IV	40 ppm	3283876
5	V	50 ppm	4144232
Correlation Coefficient			0.99916

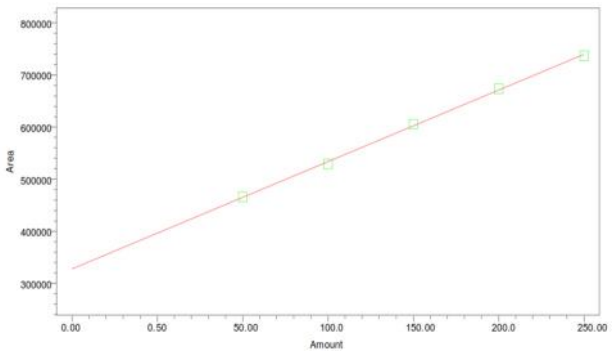

Figure 1 Calibration curve of Tamsulosin

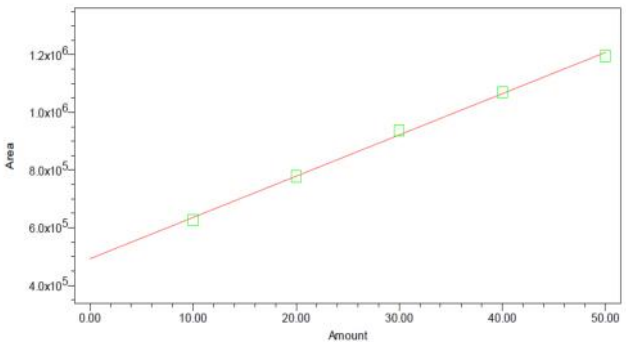

Figure 2 Calibration curve of Finasteride

Table 3 Calibration parameters for Tamsulosin and Finasteride

Parameter	Results for Tamsulosin	Results for Finasteride
Slope	19718	14311
Intercept	65498	49120
Correlation co-efficient	0 .9993	0.99916

Table 4 Sample Chromatogram values for Repeatability

	Peak name	RT	Area
1	Tamsulosin	2.321	2235319
2	Tamsulosin	2.317	2240678
3	Tamsulosin	2.323	2249490
4	Tamsulosin	2.322	2245822
5	Tamsulosin	2.324	2251694
Mean			2244601
Std.dev			6656.8
%RSD			0.3

Table 5 Sample Chromatogram values for Repeatability

	Peak name	RT	Area
1	Finasteride	4.304	1501417
2	Finasteride	4.300	1486940
3	Finasteride	4.308	1490656
4	Finasteride	4.310	1487329
5	Finasteride	4.314	1490384
Mean			1491345
Std.dev			5881.4
%RSD			0.39

Table 6 Sample Chromatogram values for intermediate Precision

	Peak name	RT	Area
1	Tamsulosin	2.328	2194758
2	Tamsulosin	2.326	2195700
3	Tamsulosin	2.327	2196191
4	Tamsulosin	2.327	2195326
5	Tamsulosin	2.331	2200951
Mean			2196585
Std.dev			2496.0
%RSD			0.1

Table 7 Sample Chromatogram values for intermediate Precision

	Peak name	RT	Area
1	Finasteride	4.335	1456296
2	Finasteride	4.336	1457422
3	Finasteride	4.334	1456513
4	Finasteride	4.337	1454579
5	Finasteride	4.340	1451483
Mean			1455259
Std.dev			2347.6
%RSD			0.16

Table 8 Chromatogram Values for Accuracy of Tamsulosin

Sample No.	Spike Level	Amount (µg/ml) added	Amount (µg/ml) found	% Recovery	Mean % Recovery
1	50 %	5	4.9	98%	**100%**
		5	5.1	102%	
		5	5	100%	
2	100 %	10	9.88	98.8%	**99.13%**
		10	9.91	99.1%	
		10	9.95	99.5%	
3	150 %	15	14.89	99.2%	**99.69%**
		15	14.86	99.0%	
		15	**14.82**	**99.79%**	

Table 9 Chromatogram Values for Accuracy of Finasteride

Sample No.	Spike Level	Amount (µg/ml) added	Amount (µg/ml) found	% Recovery	Mean % Recovery
1	50 %	5	4.9	98%	**100%**
		5	5.1	102%	
		5	5	100%	
2	100 %	10	9.88	98.8%	**99.31%**
		10	9.91	99.1%	
		10	9.95	99.5%	
3	150 %	15	14.89	99.2%	**99.89%**
		15	14.86	99.0%	
		15	**14.99**	**99.79%**	

Table 10 Robustness results for Finasteride (flow rate)

S.No	Flow Rate(ml/min)	System suitability results	
		USP Plate count	USP Tailing
3	1.2	2686	1.3

Table 11 Robustness results for Tamsulosin (flow rate)

S.No	Flow Rate (ml/min)	System suitability results	
		USP Plate count	USP Tailing
1	0.8	2231	1.3
2	1.0	2114	1.3
3	1.2	2063	1.3

4. Conclusion

A new method was established for simultaneous estimation of Tamsulosin and Finasteride by RP-HPLC method. The chromatographic conditions were successfully developed for the separation of Tamsulosin and Finasteride by using Agilent C18 column (4.6×150mm)

5µ, flow rate was 1ml/min, mobile phase ratio was (60:40 v/v) methanol: Phosphate buffer pH 3.0, detection wavelength was 256 nm. The retention times were found to be 2.327 mins and 4.342 mins. The % purity of Tamsulosin and Finasteride was found to be 99.84% and 100.14% respectively. The system suitability parameters for Tamsulosin and Finasteride such as theoretical plates and tailing factor were found to be 2937, 1.3 and 2300 and 1.3, the resolution was found to be 4.6. The analytical method was validated according to ICH guidelines (ICH, Q2 (R1)). The linearity study of Tamsulosin and Finasteride was found in concentration range of 50µg-250µg and 10µg-50µg and correlation coefficient (r^2) was found to be 0.999 and 0.999, % recovery was found to be 100.07% and 100.06%, %RSD for repeatability was 0.3 and 0.39, % RSD for intermediate precision was 0.1 and 0.16 respectively. The precision study was precision, robustness and repeatabilty. LOD value was 3.041 and 3.08 and LOQ value was 9.79 and 10.37 respectively. Hence the suggested RP-HPLC method can be used for routine analysis of Tamsulosin and Finasteride in API and Pharmaceutical dosage form.

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